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K022777

510(k) Summary

8/16/02

Onux Medical, Inc.. Contact Person:	Ruthann DePietro
Trade or Proprietary Name:	To be determined (Manual Touché)
Common or Usual Name:	Endoluminal suturing system
Classification Name:	Suture, nonabsorbable, steel, monofilament and multifilament

Devices to Which Equivalence is Claimed

The present device is substantially equivalent to the Powered Touché Suturing System and the Salute Fixation System.

Description of Subject Device

A single-use, surgical instrument for placing stainless steel sutures.

Intended Use of Subject Device

The Manual Touché Suturing System has applications in gynecological, orthopaedic, and general abdominal; endoluminal, open and thoracic endoscopic surgical wound closure procedures (e.g. creation of anastomosis, hernia repair, ligation and hemostasis).

Comparison of Technical Aspects

	Powered Touché	Manual Touché	Salute
Wire drive	Battery operated/dc motor	Manual	Manual
Wire type	316 L Stainless steel	316 L Stainless steel	316 L Stainless steel
Wire diameter	4-0 USP .006 in. wire	4-0 USP .006 in. wire	.017 or .018 in. wire
Device usage	Reusable/Disposable	Disposable	Reusable/Disposable
Jaw manipulation	Manual	Manual	N/A
Jaw rotation	Battery operated/dc motor	Manual	Battery operated/dc motor

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2002

Ms. Ruthann DePietro
Vice President, Quality
and Regulatory Affairs
Onux Medical, Inc.
5 Merrill Drive
Hampton, NH 03842

Re: K022777
Trade/Device Name: The Manual Touché Suturing System
Regulation Number: 878.4495 and 878.4800
Regulation Name: Stainless steel suture, Manual surgical instrument for general use
Regulatory Class: II
Product Code: GAQ, HCF
Dated: August 16, 2002
Received: August 21, 2002

Dear Ms. DePietro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

INDICATIONS

The Manual Touché Suturing System has applications in gynecological, orthopaedic, and general abdominal; endoluminal, open and thoracic endoscopic surgical wound closure procedures (e.g. creation of anastomosis, hernia repair, ligation and hemostasis).

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022777